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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,769

12/05/2005

Rainer Klocke

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5191

7590 03/17/2008  
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EXAMINER

KOLKER, DANIEL E

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,769	<b>Applicant(s)</b> KLOCKE ET AL.	
	<b>Examiner</b> DANIEL KOLKER	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-2,4,6,8-11,14-19,21,23,27-28,31-39,44,46,49,79,81-82,85-87,89,92,96-100,122-125,152,154-158,161,163-183,186-195,209-217 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6,8-11,14-19,21,23,27,28,31-39,44,46,49,79,81,82,85-87,89,92,96-100,122-125,152,154-158,161,163-183,186-195 and 209-217.

### **DETAILED ACTION**

1. The preliminary amendment filed 22 February 2008 has been entered.
2. Applicant is advised that claim 33 has been included in group 1 for the purposes of restriction. Claim 33 does not depend from any claim as presently written; should group 1 be elected applicant may want to amend claim 33 so that it in fact depends from a pending claim.
3. Applicant is advised that claim 183 literally depends from claim 175, but is drawn to a support comprising oligonucleotides. As claim 175 is a method and not drawn to oligonucleotide products, claim 183 has been grouped with other claims drawn to oligonucleotides for the purposes of restriction.

### ***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 – 2, 4, 6, 8 – 11, 14 – 19, 21, 23, 27 – 28, 31 – 39, 44, 46, 79, 81, 186 – 190, and 209 – 213, drawn to polypeptides and methods of administering same.

Group 2, claim(s) 46, 49, and 191 – 195, drawn to nucleic acids.

Group 3, claim(s) 82 and 85, drawn to methods of diagnosing subjects comprising comparing expression levels of cytoplasmic dynein heavy chain 1 polypeptide against a reference value.

Group 4, claim(s) 86 – 87, 89, 92, 96 – 100, 214 – 216, drawn to methods of diagnosing subjects comprising determining that nucleic acid samples comprise mutations in the nucleic acid sequence of a polynucleotide.

Group 5, claim(s) 122 – 125, 152, 154 - 158, 161, 163 - 174, drawn to methods comprising identifying protein or nucleic acid markers.

Group 6, claim(s) 176 – 183 and 217, drawn to oligonucleotides.

The inventions listed as Groups 1 – 6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature of group 1 is protein; this group includes both claims drawn to this product and methods of administering the product to

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subjects (i.e. the first claimed method of using the product). The claims in the remaining groups are drawn to different technical features. The technical feature of group 1 is not present in the claims of groups 2 - 6, and the technical features of groups 2 – 6 are not present in the group 1 claims. Thus unity of invention is lacking. Note that PCT Rule 13 does not allow for multiple products or methods in a single application.

***Requirement for Further Restriction***

5. The pending claims recite or encompass multiple products, specifically multiple patentably distinct nucleic acid and amino acid sequences. Each sequence is a unique product, with unique biochemical properties (i.e., technical features) and which cannot be substituted for any other such product. Additionally, separate search of the electronic databases is required for each and every individual sequence. Thus consideration of multiple products or methods of using multiple products would be burdensome.

Therefore, in order to be completely responsive to this restriction requirement, should applicant elect any group that encompasses multiple patentably distinct sequences or methods of using same, applicant must elect a single nucleic acid or amino acid sequence to be searched.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

March 3, 2008